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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. 2:15-MD-02641-DGC

DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION *IN LIMINE* NO. 3 TO EXCLUDE EVIDENCE OF FDA WARNING LETTER

(Assigned to the Honorable David G. Campbell)

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Bard moves *in limine* to exclude any evidence concerning the July 13, 2015 FDA Warning Letter.[1] *See* Exhibit A. Evidence of the Warning Letter should be excluded because (a) it is an irrelevant, informal advisory statement by FDA that does not constitute a final agency action, (b) the prejudicial effect of the FDA Warning Letter substantially outweighs any probative value, and (c) it is inadmissible hearsay. The Warning Letter was issued ***more than eight years after*** Plaintiff received her G2® Filter in 2007. The following chart categorizes the issues raised in the Warning Letter and illustrates how it is not relevant[2]:

Warning Letter Item Nos.	Why it Is Not Relevant
Nos. 1 and 2 regarding the Recovery Cone	• Plaintiff makes no allegations that the Recovery Cone caused or contributed to her injuries.
Nos. 4(b), 5, and 6 regarding the manufacturing process of the Denali Filter	• Plaintiff did not receive a Denali Filter, and any criticism by FDA regarding the manufacturing process of the Denali Filter has absolutely no impact on this case.
No. 4(a) regarding cleaning process of Bard's filters	• Plaintiff has made no allegation that her G2 Filter suffered from some alleged inadequate cleaning process.
Nos. 3, 7, 8 regarding Bard's complaint handling and MDR reporting procedures	• Although the FDA raised questions regarding Bard's complaint handling and medical device reporting practices, none of FDA's concerns impact the accuracy or integrity of Bard's complication rate calculations.[3] • While the FDA questioned a handful of Bard's categorizations of MDR reports that are published on FDA's MAUDE database, there is no evidence that the implanting physician, Dr. D'Ayala, relied upon information on the MAUDE database when deciding to use the G2 in or before 2007.

ARGUMENT AND CITATION OF AUTHORITY

The FDA Warning Letter is a red herring that has no relevance to this case. Instead,

[1] Counsel for Defendants conferred with counsel for Plaintiffs and this motion is opposed.
[2] Bard refers the Court to, and incorporates by reference here, the background information concerning the Warning Letter provided in Defendants' Memorandum at Doc. 693.
[3] In its prior briefing, Bard explained why FDA's questions do not impact the integrity or accuracy of Bard's internal trending and rate analyses. *See, e.g.*, Doc. 693 at 11-15.

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it has the strong potential to cause extreme prejudice to Bard and to confuse the jury.

First, the Warning Letter is an irrelevant, "informal" "advisory" statement by FDA that does not constitute a "final agency action" or determination. *See* Chapter 4 of FDA's Regulatory Procedures Manual[4] at p. 4-2 to 4-3; *see also Dietary Supp. Coalition, Inc. v. Sullivan*, 978 F.2d 560, 562–63 (9th Cir. 1992) ("[T]he type of informal letter issued by the FDA . . . does not constitute . . . formal or final agency action." (internal quotation marks omitted)). The Warning Letter does not tend to prove or disprove a material fact for the simple reason that it is not a final agency determination or opinion on the matters expressed therein. Additionally, as shown by the chart above, the Warning Letter does not tend to prove or disprove a material fact because nothing in the Letter constitutes a criticism of the design or labeling of the G2. When a Warning Letter does not tend to prove or disprove a material fact, it should be excluded as irrelevant. *See, e.g.*, *In re Seroquel Prod. Liab. Litig.*, No. 6:06MD1769-ORL-22DAB, 2009 WL 223140, at *5 (M.D. Fla. Jan. 30, 2009); *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 966–67 (D. Minn. 2009) (finding that three FDA letters regarding Viagra advertisements were irrelevant and inadmissible because two of the letters were issued after Plaintiff stopped using Viagra and there was no evidence Plaintiff saw the advertisements in the third).

Second, the Court should exclude evidence of the Warning Letter under Rule 403, because any probative value is substantially outweighed by the danger of unfair prejudice to Bard, misleading the jury, and wasting time. Many courts have expressed concern that reports issued by governmental agencies, because of their "official" nature, may cause a jury to give the evidence inordinate weight. *Johnson v. Ford Motor Co.*, 988 F.2d 573 (5th Cir. 1993); *see also, e.g., Black v. Ryder/P.I.E. Nationwide, Inc.*, 15 F.3d 573, 587 (6th Cir. 1994) (decision by the NLRB properly excluded because "the jury would be quite likely to assign greater value to this decision than it is worth, given that it is the product only of an administrative investigation, and not of an adjudicatory procedure"). Because

[4] *Available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ (last accessed 1/19/2018).

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of the heightened risk of prejudice associated with government reports, such as Warning Letters, courts have excluded Warning Letters because their probative value is substantially outweighed by the prejudicial effect. *See, e.g.*, *Ortho-McNeil-Janssen Pharm., Inc. v. State*, 432 S.W.3d 563, 580 (Ark. 2014) (reversing judgment of the trial court in favor of plaintiff based in part on trial court's erroneous admission of an FDA Warning Letter, noting that the letter is "more prejudicial than probative"); *Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 4460011, at *18 (N.D. Ill. Mar. 29, 2013) (excluding FDA Warning Letter on the grounds that it is "highly prejudicial").

Here, if Plaintiff were allowed to introduce evidence regarding the Warning Letter, it would unfairly suggest to the jury that wrongdoing must have occurred simply because the FDA got involved, even though the Warning Letter has no bearing on the issues in this case. Additionally, introduction of the Warning Letter would require Bard to spend an inordinate amount of time putting the it into proper context, explaining to the jury that it is not a final agency determination, that the FDA's assertions do not impact Plaintiff's allegations, and the rigorous actions Bard undertook in response to the Warning Letter.

Third, the Warning Letter is inadmissible hearsay, and it does not fall within any hearsay exception, including without limitation Rule 803(8)'s "Public Records" exception. Rule 803(8) applies only to official or formal activities of the FDA "setting forth the activities" of the FDA, not to "preliminary or interim evaluative opinions of agency staff members" such as those expressed in the Warning Letter. *See Smith v. Isuzu Motors, Ltd.*, 137 F. 3d 859, 862 (5th Cir. 1998). Because the Warning Letter constitutes an informal and preliminary statement by FDA, it does not fall within Rule 803(8)'s hearsay exception. *See, e.g.*, *Toole v. McClintock*, 999 F.2d 1430, 1434 (11th Cir. 1993) (preliminary "FDA report is not the kind of trustworthy report described in Rule 803").

CONCLUSION

For the foregoing reasons, Bard respectfully moves for an entry of an *in limine* order to exclude any evidence regarding the July 13, 2015 FDA Warning Letter issued to Bard.

RESPECTFULLY SUBMITTED this 26th day of January, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of January, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

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